Garbo Lobster
We put our name on it

January 6, 2005

Dockets Management Branch (HFA-305)
Attn: Docket No. 2004D-0510
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: COMMENTS ON DRAFT GUIDANCE ENTITLED "PROPOSED REFERRAL PROGRAM FROM THE FOOD AND DRUG ADMINISTRATION TO THE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION SEAFOOD INSPECTION PROGRAM FOR THE CERTIFICATION OF LIVE AND PERISHABLE FISH AND FISHERY PRODUCTS FOR EXPORT TO THE EUROPEAN UNION AND THE EUROPEAN FREE TRADE ASSOCIATION [DOCKET NO. 2004D-0510]

Dear Sir or Madam:

Garbo Lobster Company, Inc. is a U.S. owned business engaged in the export of live lobsters to countries in the European Union (EU). Our main office and packing facility is located in Groton, Connecticut and we also own a large lobster pound located in Hancock, Maine. For more than 20 years we have purchased lobsters from New England fishermen and exported them live to Europe. We employ more than 30 people at our two facilities and provide millions of dollars of business each year to our suppliers and transportation service providers.

Garbo Lobster is one of the nation's largest exporters of live lobsters. Our facilities are registered with the FDA, we have our own Central File Number (CFN) and we have been on the FDA's EU Export Certificate List since its inception. We operate our facilities under the FDA's Hazard Analysis Critical Control Point (HACCP) program and are inspected on a regular basis by FDA inspectors. Because we ship almost exclusively to the EU we are very familiar with the EU seafood safety requirements.

Garbo Lobster Company, Inc. 415 Thames Street Groton, CT 06340
(860) 449-9380 Fax (860) 449-9389
Garbo Lobster Limited Deer Island New Brunswick Canada

2004D-0510 C3

Over the years we have worked closely with the FDA's New England District to ensure that our company meets all the EU seafood safety and HACCP requirements and receives the required EU Export Health Certificates (Certificates) on a timely basis. Last year our company needed approximately 1200 of these certificates to satisfy customer demand.

Garbo Lobster is strongly opposed to the proposed referral program that will "test the viability and effectiveness of the arrangement" for a 24-month period. Our multi-million dollar export business is totally reliant on obtaining Certificates almost simultaneously with the receipt of an order from overseas. The current system has worked well and the FDA has had no problems verifying and attesting (through the issuance of a Certificate) that our lobsters are packed under HACCP. We do not believe that the government should conduct an experiment with the future of our business at stake. Any disruption or change in the ability of Garbo Lobster to obtain Certificates in a timely manner will most certainly mean a loss of customers and business. Our opposition is more fully explained below:

Background

The live lobster export business is extremely risky, particularly since it involves shipping a live and perishable product overseas. Lobsters can only live in shipping containers for a short period of time so every hour is critical. Traffic delays, cancelled air flights, weather or the inability to obtain a Certificate can all translate into the loss of hundreds of thousands of dollars.

The export of live lobsters to the EU is a competitive business, not only within the U.S. but with Canada. U.S. companies compete daily with Canadian export companies who generally have a much lower cost of production (Canadian export companies receive Certificates at no charge from their government). U.S. companies are able to compete because our superior transportation services allow us to get a quality product to the customer more quickly. Garbo Lobster ships airfreight out of the three major airports serving the NY/NJ area.

Typically Garbo Lobster will receive orders from our primary EU customers at approximately 4 a.m. (EST). These order will be filled (lobsters packed in shipping cartons) and shipped (paperwork and product put in trucks headed to the airport) no later than 8 or 9 a.m. that same morning. The lobsters will be received by our European customers within 24 hours after packing. We are able to maintain a high product quality and avoid dead loss (lobsters can die during shipping) because of our rigid schedule.

FDA's NE Certificate Program

Since 1996, the FDA's NE District has developed and implemented an effective Certificate Program. The District has issued Program Instructions which more fully detail the responsibilities of industry and how the FDA will process Certificate requests. In accordance with these instructions, Garbo Lobster is able to obtain Certificates for exports prior to the actual shipment date. Generally we request approval of a batch of certificates once a week.

Because we essentially ship to the same companies every week, we are able to fill out (except date and weight) a completed Certificate (as required by the instructions) which is then reviewed and approved by the FDA. Garbo Lobster provides the FDA with prepaid express packages, as required, and then provides it with a copy of the Certificate after it is used. The ability to receive Certificates in advance is critical to our ability to process our orders when needed. Since we fill out all the Certificates and pay for the cost of shipping, the FDA's cost is limited to that associated with stamping or processing the Certificates and putting them in overnight mail.

Proposed 24-Month Experiment

In its November 26, 2004 Federal Register Notice (Notice), the FDA claims that it is "proposing to operate a Referral Program for a 24-month period to test the viability and effectiveness of such an arrangement". Garbo Lobster strongly objects to this so-called test as it has the potential to destroy our business by interrupting or eliminating our ability to obtain Certificates on a timely basis. We can not support a test or experiment that places our business in jeopardy. Moreover, the FDA has provided no assurances, either in its Notice or in its Guidance to Industry, that businesses will be able to receive the necessary Certificates from the Department of Commerce (DOC) in the same timely manner as they do today from the FDA.

Transfer to DOC SIP

The FDA is proposing to transfer its responsibility for issuing Certificates to the Department of Commerce's Seafood Inspection Program (SIP). The SIP currently issues Certificates to its clients (only) under a voluntary fee-for-service program authorized by the Agricultural Marketing Act of 1946 (7 U.S.C. §§ 1621-27) (AMA). While the FDA proposes to transfer the clerical duties of issuing Certificates, it contends that the "basis for issuing EU Export Certificates under the Referral Program would be, as it is now, whether the establishment or establishments in question are in regulatory good standing with the FDA". In other words, the FDA proposes that NOAA not exercise any independent judgment in issuing Certificates and so long as an establishment is on an FDA EU Export Certificate List it shall receive requested Certificates. While we think we understand the desired result of this proposal (to provide industry with assurances that nothing will change) we do not believe the FDA has the legal authority to place such constraints on another Federal agency without its concurrence.

The FDA has also made it clear in the Guidance that it intends to continue to serve as the primary competent authority for all EU-related Export Certificate Services for fish and fishery products covered by the referral program. In addition, it will retain the authority to determine whether establishments are eligible to be placed on the lists, it will maintain the EU Export Certificate Lists and it will provide these lists to the EU. It is quite clear that the FDA desires to maintain authority and control over the Certificate program while at the same time divorcing itself from the responsibility for issuing the actual Certificates for live and fresh products.

DOC SIP/FDA HACCP Programs Quite Different

Garbo Lobster, like all other seafood processors, was required by the FDA to implement a HACCP food safety program in 1997 under the authority of the Federal Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.). This program was developed and implemented by the FDA because of seafood safety concerns and because of the agency's statutory obligation to ensure that all food intended for human consumption is safe. As stated in the FDA's final regulations implementing the mandatory HACCP program, the FDCA provides a broad statutory framework to the FDA for Federal regulation to ensure human food will not be injurious to health and to prevent commerce in adulterated foods. "Given its responsibility under the act, FDA has concluded that it is necessary to require that firms incorporate certain basic measures into how they process seafood". Seafood that is not processed under a HACCP program will be deemed "adulterated" under the FDCA which in turn subjects the processor to serious fines and penalties. Consequently, the regulations implementing the mandatory program (21 C.F.R. § 123) require that we operate our facilities in accordance with the FDA's HACCP regulations and that our facilities are periodically inspected by an FDA food safety inspector (or an inspector from another governmental entity with which FDA has a contract, partnership arrangement or other MOU for the purpose of conducing inspections for the FDA). Since 1997 we have followed the FDA's rules, have been regularly inspected and have been in regulatory good standing with the agency. From its inception in 1996, the single focus of the FDA HACCP program has been to ensure the safety of seafood processed in the U.S.

On the other hand, the DOC SIP operates under the authority transferred to the Secretary of Commerce by the Secretary of Agriculture to implement the Agricultural Marketing Act of 1946 (7 U.S.C. §§ 1621-27) for fish and seafood products.[1] The AMA was enacted to promote the "marketing, handling, storage, processing, transportation and distribution of agricultural goods" (§1621). The AMA directed the Secretary to "develop and improve standards of quality, condition, quantity, grade, packaging" and "to inspect, certify, and identify class, quality, quantity and condition of agricultural products when shipped" (§ 1622). As its name suggests, the AMA's primary focus is on the marketing and promotion of products (not food safety) and for more than 30 years the DOC SIP program has successfully offered its clients a variety of marketing, grading and inspection services. Interestingly in the US DOC Inspector General's Report (Audit Report No. STL-9607-8-0001/September 1998), the primary reason for the Inspector General (IG) recommending that NOAA divest itself of the seafood inspection program was that it

[1] All functions of the Department of Agriculture which pertain to fish, shellfish, and any products thereof, now performed under the authority of title II of the Act of August 14, 1946, as amended (7 U.S.C. 1621-27) including but not limited to the development and promulgation of grade standards, the inspection and certification, and improvements of transportation facilities and rates for fish and shellfish and any product thereof, were transferred to the Department of Interior by the Director of the Budget (23 FR 2304) pursuant to section 6(a) of the Act of Aug.,8, 1956 (16 U.S.C. 742e). Reorganization Plan No. 4of 1970 (84 Stat. 2090) transferred, among other things, such functions from the U.S. Department of the Interior to the U.S. Department of Commerce.

was not related to NOAA's core mission. The IG accurately observed that the "inspection program mission is to determine *quality* by inspecting, measuring, and testing seafood, and to certify the product's wholesomeness" (p. i). The DOC SIP program was not designed and has not focused on food safety as this is the responsibility of FDA.

The FDA's seafood safety HACCP program is dramatically different than the services offered by the DOC SIP. Indeed, the DOC SIP proudly advertises on its web site a comparison of the FDA HACCP program and its own. This site accurately depicts the FDA program as a "safety" program while the DOC SIP services go far beyond safety and include wholesomeness, economic integrity, and quality assurances among others. Because the DOC SIP draws its legal authority from the AMA and has historically focused on marketing activities (e.g., grading), it understandably offers many important services to industry that go far beyond safety. And while these services are clearly important to many in the seafood industry, they are not needed or wanted by single product exporters of live lobsters. Because of the uniqueness of our product, grading and wholesomeness and even economic integrity issues are not of major concern to our customers. These issues are dealt with in commercial or business terms. Health Certificates, on the other hand, are of paramount concern and because they can only be issued by a competent government agency, exporters like Garbo Lobster are at the mercy of our government agencies. Our business will fail if we are unable to obtain Certificates when we need them.

FDA's Referral Program Creates Two Different Standards

In its Notice, the FDA states, "The basis for issuing EU Export Health Certificates under the Referral Program would be, as it is now, whether the establishment or establishments in question are in regulatory good standing with FDA". However, the agency has failed to explain how the DOC SIP can issue Certificates under two different standards.

Unlike FDA, the DOC SIP only issues certificates to clients enrolled in its inspection programs.

As explained above, Garbo Lobster does not participate in this program because it is not needed and the services go far beyond those requested or required by our customers. The FDA proposal would require the DOC SIP to amend its policies so that non-clients in good regulatory standing with FDA could also receive Certificates. We question whether the DOC SIP can legally issue the same document using two different standards. In addition, FDA has not provided any information or guidance from the DOC SIP that it intends to change its policy. In the absence of such assurances, Garbo Lobster and other exporters would be forced to subscribe to expensive DOC inspection services (that are not needed or wanted for the export of live lobsters) in order to receive Certificates that should be issued by the FDA.

DOC SIP Does Not Provide Advance Receipt of Certificates Like FDA

As discussed above, the FDA's New England Health Certificate Program allows exporters to receive Certificates in advance of shipments because it is the

only practical and effective method to ensure that export businesses can satisfy the EU's health Certificate requirement. Unfortunately, the DOC SIP has not adopted a similar policy and does not allow industry to obtain official Certificates prior to the date of shipment. This is the primary reason why exporters like Garbo Lobster rely so heavily on the FDA. Ironically, the FDA has adopted procedures more friendly to business than the DOC which is much more of a promotional agency. As outlined above, the inability to receive Certificates in advance of shipment will ruin Garbo Lobster and other exporters.

Referral Program Cost Not Quantified As Required

The FDA has failed to explain the cost of the Proposed Referral Program and has ignored the potential multi-million dollar losses which could be incurred by industry as a result of this experiment. In its November 2004 FDA Guidance on EU Export Certificates for Seafood Questions and Answers, the agency refers the public to the National Oceanic and Atmospheric Administration (NOAA) web site for costs. However, the NOAA SIP website does not identify the fee for the issuance of Certificates for non-participating establishments. Instead the DOC SIP identifies per hour fees (regular time, overtime and Sunday and Holidays) and charges for official establishment and product inspection services, lot inspections, sanitation services and consultative services. These fees range from approximately $62-$224 per hour.

If as it appears, all live lobster exporters would be required by the FDA Referral Program to sign a contract with the DOC SIP, enroll in its inspection program and pay for certificates, the cost to industry would be in the millions of dollars. My business can not afford these costs if we are to remain competitive with Canadian suppliers who receive Certificates free of charge. If the DOC SIP does not reform its procedures to allow industry to obtain Certificates prior to shipment, the cost of the Referral Program will be in the hundreds of millions of dollars in collapsed export businesses.

Costs Do Not Justify Benefits

The FDA contends that "the demand for EU Export Certificates by industry has risen dramatically in recent years and has caused significant resource allocation problems for FDA". While we are sympathetic to this situation, we do not believe and the FDA has not explained how the Proposed Referral Program will alleviate this situation. Specifically, the FDA intends (1) to continue to serve as the primary competent authority for all EU-related Export Certificate services and provide guidance and oversight to the NOAA SIP program; (2) to establish criteria for determining whether U.S. establishments are eligible to receive EU Export Certificates based on whether the establishments are in regulatory good standing with the FDA; (3) to maintain an up-to-date database on the current regulatory status of establishments; (4) to continue to provide EU Health Certificates for shipments of frozen, canned, dried, smoked, and vacuum packed fishery products; and (5) to continue to perform establishment inspections.

Indeed, the only service the FDA said it is proposing to refer is the actual *issuance* of Certificates for live and fresh fish products, which is just a small part of the overall program. In accordance with FDA instructions, private companies like

Garbo Lobster prepare (fill-out) the Certificates for review by the agency. Once a completed Certificate is received by the FDA, "it will be reviewed and, if acceptable, identified with a unique shipment number". The agency then mails these Certificates back to the appropriate establishment in postage-paid envelopes. Since the agency is only proposing to refer this clerical function, we do not believe that the cost savings justifies the incredible costs the proposal will impose on industry.

Proposed FDA Cost Recovery Solution

While no business likes to increase its costs and become less competitive in the process, Garbo Lobster would support FDA imposing a reasonable fee ($15-$25) for the issuance of Certificates. While we are aware that it only takes minutes to verify and issue a Certificate, we believe such an approach would go farther in help FDA address its resource problems than the Proposed Referral Program. Based on this proposed fee and the number of Certificates Garbo Lobster received last year, fees from our business alone would pay for the cost ($30,000) of an additional staff member to process Certificates. If FDA does not have the authority to charge such a fee we would support congressional action to provide it with this authority.

Conclusion

The stated goal of the FDA's Guidance is "to expedite the transportation of live and perishable fish and fishery products". Unfortunately, in our view the Proposed Referral Program will have the exact opposite effect. At best the Proposed Referral Program will impose millions of dollars of new costs (including lost sales) onto industry and at worst it will destroy the U.S. live lobster export business. I urge the FDA not to go forward with the Proposed Referral Program for the reasons addressed above and instead seek its own cost recovery program as proposed by my company. We also support the comments submitted by Mr. Michael Tourkistas of East Coast Lobster Company.

Lastly, I and other members of the lobster export business would like to request a meeting with the FDA to discuss these issues prior to the agency making decisions.

Sincerely,

David Garbo
President